Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY
Tel. +49 (0)89 2399 - 0
Fax +49 (0)89 2399 - 4465

Smee, Anthony James Michael
Gill Jennings & Every LLP
Broadgate House
7 Eldon Street
London EC2M 7LH
GRANDE BRETAGNE

Formalities Officer
Name: Sommermeyer
Tel.: 7677
or call:
+31 (0)70 340 45 00

Date: 07-05-2010

Reference	Application No./Patent No.
MJB07874EP	04709953.6 - 2201 / 1593073

Applicant/Proprietor
Pharmasea International Pty Ltd.

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent application.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will not be public, will take place before the Examining Division.

on 29.09.10 at 09.00 hrs at the EPO,
PschorrHöfe, Bayerstr. 34, D-80335 München

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 1/2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC, see also OJ EPO 10/2008, 471).

Your attention is drawn to Rule 4 EPC, regarding the language of the oral proceedings, and to the Special edition No. 3 OJ EPO 2007, L.1., concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

The final date for making written submissions and/or amendments (R. 116 EPC) is 27.08.10.

The actual room number as well as the waiting room numbers will be given to you by the porter in the foyer at the above EPO address.

Parking is available free of charge in the underground car park. However, this applies only in the case of accessing the car park via the entrance "Zollstrasse".

1st Examiner:	2nd Examiner:	Chairman:
Kürten I	Sisk A	Barba M

For the Examining Division

Annexes:
Confirmation of receipt (Form 2936)
Communication (EPO Form 2906)

Europäisches Patentamt • European Patent Office • Office européen des brevets

Registered letter with advice of delivery

to EPO postal service: 03.05.10

The examination is being carried out on the **following application documents**

Description, Pages

3-5, 7-11	as published			
1, 2A, 2B, 6, 6A	filed in electronic form on			10-10-2007
2	received on	28-07-2009	with letter of	28-07-2009

Claims, Numbers

1-21	as published	
1 - 21	filed in electronic form on	10-10-2007

Drawings, Sheets

1/2, 2/2	as published

1 Oral Proceedings

Since the arguments presented by the Applicant in his letter of 28.07.2009 are not considered convincing, and since the Applicant has requested that Oral Proceedings according to Article 116 EPC be held in the event that the Examining Division intends to issue a decision unfavourable to him, it would appear to be expedient to hold such proceedings at this stage of the procedure. The Applicant should bear in mind that it is intended to reach a conclusion to the examination procedure at the end of the Oral Proceedings, resulting in either the refusal of the application or agreement on the text for grant of a patent. The main issues to be discussed at the Oral Proceedings are indicated below.

2 Prior art

The following document is cited by the Examiner (see Guidelines C-VI, 8.2 and 8.3). A copy of the document is annexed to the communication and the numbering will be adhered to in the rest of the procedure:

D4: Book "Biometrics: Personal Identification in Networked Society"; eds. Jain A. et al; Kluwer Academic Publishers, US; 1999; pages 20 - 21, 30 - 33, 321 - 322.

D4 is an excerpt from a book considered to represent a part of the common knowledge of the skilled person in the art at the priority date of the application.

The attention of the Applicant is drawn to the fact that the introduction of prior art documents at this stage of the procedure does not constitute any procedural violation, see e.g. decision T0166/04 of the Boards of Appeal, especially paragraphs 2 to 4 of the item "Reasons for the Decision".

3 Inventive step (Article 56 EPC)

The Examining Division is still of the opinion that the subject-matter of the present set of claims does not involve an inventive step.

3.1 Claim 1:

3.1.1 Document D2 is considered to be the prior art closest to the subject-matter of claim 1. D2 discloses:

A computerised identity matching management process, the process comprising the steps of:

a management computer receiving a request, from capture apparatus waiting to commence a biometric capture process representative of the person to initiate the capture process (page 9, lines 25 - 31);

the management computer responding to the request to return a message to the capture apparatus at a first instant in time, the message containing a unique code, and where receipt of the message containing the code at the capture apparatus causes initiation of the capture process (page 10, lines 2 to 11);

the management computer, after returning the message, receiving a captured biometric representative of the person from the capture apparatus coded with the unique code, at a second instant in time (page 10, lines 12 - 22); and

the management computer decodes the captured biometric, initiates a matching process and if the second instant is less than a predetermined time later than the first instant (a time-out criterion has not been violated) authenticates the user (page 10, lines 23 - 30).

3.1.2 The subject-matter of claim 1 therefore differs from the method known from D2 in that:

1) In claim 1, only a biometric is supplied to the management computer, which is used to search a database of biometric records and if match is found, to retrieve an identification code of the person (person identification). In D2, the identification code is supplied in the beginning and used to retrieve the corresponding biometric record from the database (person verification).

2) The biometric in claim 1 is decoded only if the second time instant is less than a predetermined time than the first time instant, while in D2 the biometric is always decoded.

3) The biometric authentication in claim 1 is used for the supply for pharmaceutical substances to the authenticated person, while D2 does not disclose a particular use of the authentication process. In particular, claim 1 discloses:

3.1) retrieving a date stamp and using the identification code to retrieve a stored data record of the person which includes at least a substance the person is prescribed, a quantity in which the substance is to be supplied and a date at which the substance is to be supplied, wherein the stored data records are logically separate from the biometric records;

3.2) determining whether the date stamp matches the date at which the substance is supplied, and if a match is determined, supplying the substance in the prescribed quantity and recording information to form a record to update the supply of the substance to the person.

First, each of the distinguishing features 1) to 3) will be addressed separately.

3.1.3 The effect produced by the first difference is that the **person is identified** (its identity code is retrieved) based on the person's biometric data. By contrast, in D2 the identity of the **person is verified** (checks whether supplied biometric data corresponds to a supplied ID).

It is generally known in the art that person identification and verification are two related problems that can be solved with the same technology (cf. D4, page 20, line 38 to page 21, line 13). Depending on the available data and user requirements a person can either be identified or its identity verified. In the verification case, the person's biometric data is supplied with an identity claim (e.g. identifier, name or bank account, see the introductory part of D2) and the supplied biometric is compared to a single database record corresponding to the supplied id, whereas in the identification case the person's biometric data is supplied only and has to be compared against all database records. Thus, if the identity of the person requesting authentication is known (as in the present case), either method can be used. In the present

case, it seems that person identification is arbitrarily chosen. There are no unexpected or advantageous effects associated with the choice of person identification (compared to the choice of person verification) apart from removing the well known discomfort of the necessity to memorize a PIN or to carry an identity card.

In conclusion, the first distinguishing features is considered to be one of multiple straightforward possibilities from which the skilled person would choose in order to authenticate the person based on his/her biometric data.

3.1.4 The effect produced by the second difference is that the time for decoding the biometric is spared if the second time-instance is not less than a predetermined time later than the first instant. Note that both in claim 1 as well as in D2, authentification does not succeed if the second time-instance is not less than a predetermined time later than the first instant.

However, the time for decoding is usually negligible (compared to the time needed in a database search to identify a person based on its biometric). Consequently, the second distinguishing feature is considered to be a minor implementation detail within the normal competence of a person skilled in the art and, therefore, not contributing to inventive step.

3.1.5 Distinguishing features 3.1) and 3.2) have a technical character only in so far as a database is used to store, retrieve and update a patient record that includes a prescribed substance, the quantity to be supplied and the date at which the substance is supplied. The feature of supplying the substance if there is a match between the date in the patient record and the retrieved date stamp is administrative and does not contribute to the technical character of the invention. The implementation of this feature (use a database to store, retrieve and update a record) is obvious from a technical viewpoint and is therefore not considered inventive.

The above assessment has been based on the teaching of a series of decisions of the EPO Boards of Appeal, in particular T641/00 (Two identities/ COMVIK), T172/03 (Order management/RICOH) and T258/03 (Auction method/HITACHI). According to these decisions an invention consisting of a mixture of technical and non-technical features and having a technical character as a whole is to be assessed with respect to the requirement of inventive step by taking into account only those features which contribute to said technical character whereas features making no such contribution cannot support the presence of inventive step. This means, that the features related

to the management of pharmaceutical substances using a set of administrative rules, which indeed lack technical character, cannot support the presence of inventive step.

According to decision T641/00 where a claim refers to an aim to be achieved in a non-technical field, as in the present case, this aim may legitimately appear in the formulation of the objective technical problem as part of the framework of the technical problem that is to be solved, in particular as a constraint to be met.

In the present case, the **objective technical problem** might be regarded as that of how to implement the proposed administrative scheme for supply of pharmaceutical substances to authorised people. The proposed solution (use of a database to store, retrieve and update data) is obvious from a technical point of view because it does not go beyond the concept of a mere automation using constraints imposed by the administrative aspects using conventional hardware and software.

Moreover, the use of a database for storing, retrieving and updating medical records in the context of medication supply to authorized people is known from the prior art (cf. D1, pages 11 to 12 and 17 to 18).

3.1.6 Finally, **no combined synergistic effect** is produced by the three features (paragraphs 3.1.3 to 3.1.5 above) distinguishing the subject-matter of claim 1 from the method of D2. Hence, the combination of these three features amounts to a mere aggregation which is obvious to the skilled person since the three features are obvious individually (the Guidelines C-IV, 9.5; decision of the EPO Boards of Appeal T 389/86).

3.2 Claim 17:

The subject-matter of independent claim 17 corresponds in terms of system features to that of claim 1. The objections raised in respect of this latter claim, therefore, also apply to independent claim 17 which is, thus, not allowable under Article 52(1) EPC for lack of inventive step in its subject-matter (Article 56 EPC).

3.3 Claims 2 - 16, 18 - 21:

Dependent claims 2 to 16 and 18 to 21 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to inventive step, the reasons being as follows:

With regard to claim 2, D2 discloses (page 7, lines 5-12) that the biometric data is securely stored. D2 also anticipates (page 12, lines 1-5) that the biometric records are logically or physically separated from the data records an authorized user has access to (claims 3 and 18). D2 also suggests that the method generates an image template (image characteristics, page 9, lines 11 - 17) from the captured biometric data (claims 4, 12).

With regard to the features of claims 5 and 6, it is well known to the person skilled in the art that multiple biometric traits improve the identification of a person (D4, page 33). Also, D2 states that the method is applicable to both iris and facial images (page 8, lines 18 - 19).

With regard to the features of claims 7 and 8 (corresponding system claims 19 and 20) D1 explicitly discloses a patient (page 9, lines 15 - 18) and a physician database (page 8, lines 23 - 26). D1 implicitly discloses a drug and a supplier database (pharmacy database, page 17, line 5).

Enrollment of a person (claims 9 and 10) is also disclosed by D1 (page 12, lines 7 - 16) and D2 (page 11, lines 28 - 30 and page 12, lines 1 - 5). Performing a fraud check (claim 11) prior to a new person registration is also disclosed by D1 (page 17, lines 23 - 25).

The feature of claim 13 that the predetermined time is determined according to the time required for the biometric capture process is also known from D2 (page 10, lines 29 - 30). D1 discloses (e.g. page 12, line 27) that the method is suitable for controlled substances (claim 14).

Claims 15 and 16 disclose the same person identification steps as listed in claim 1, the only difference being the type of user being identified. Hence, the same arguments as with claim 1 apply.

The feature of claim 21 is also disclosed by D2 (firewall protection, page 7, lines 5-12).

4 The Applicant's arguments

4.1 The Applicant argues that the first of the identified differences (person identification instead of verification) contributes to inventive step, the reasons given can be summarized as follows:

1) the risk of producing false positives (incorrect identifications of a patients) is reduced;

2) the non-necessity to enter a user identifier speeds up the identification process.

The Examining Division disagrees with these arguments for the following reasons.

4.2 In D2, a person to be authenticated supplies both an identifier and a biometric. It is generally known in the art that supplying multiple types of information that must all agree with the same database record reduces the risk of false positives (see also D4, the sentence bridging pages 32 and 33). As can further be seen from D4, in person identification the false positive rate increases with the database size because each additional entry in the database provides another opportunity to achieve a random match with the person biometrics supplied (page 321, line 36 to page 322, line 4). The false positive rate in person verification does not suffer from this problem.

4.3 In person identification, the time required to find a matching record is a function of the database size (D4, page 30, lines 17 to 26; D5). For small databases, it might be faster to perform identification instead of verification, but for larger databases the time required for the identification of a matching record becomes prohibitive. Hence, imposing limits on the database size to achieve a desired performance merely circumvents the problem of time efficiency by following a well-known trade-off. Moreover, the Applicant's argument for time efficiency is based on a particularly small database size that is is not mentioned anywhere in the application.

4.4 In summary, the Applicant's arguments regarding the advantage of using person identification instead of verification in the present application are not considered convincing. Hence, the choice of identification instead of verification is considered arbitrary and, therefore, not leading to inventive step.

5 Final remarks

5.1 According to Rule 116(1) EPC, the final date for making written submissions in preparation for the Oral Proceedings is fixed in the Summons. The Examining Division will exercise its discretion regarding the consideration of **new facts and evidence presented after that date and may not admit such submissions**. In exercising its discretionary power for treating late filed requests during the proceedings, the Examining Division will apply the **criterion of "clear allowability"**, that is, said requests will be considered, but they will not be admitted into the proceedings under Rule 116(1) and 137(3) EPC if they clearly do give rise to **new objections** under the EPC, or if they do not clearly meet **all outstanding objections** under the EPC.

5.2 The attention of the Applicant is drawn to the fact that the communication accompanying the summons will, as a rule, will be the last communication before the actual Oral Proceedings.

The Applicant has the possibility to file a well-reasoned complete written response to a summons. If such submissions are convincing and filed before the given deadline, and if no or only minor objections are outstanding which can be resolved in a telephone conversation, then the Oral Proceedings may be cancelled.

If however, the Examining Division considers that a decision on the matter cannot be reached on the basis of the written evidence obtained then the Oral Proceedings will be maintained and the outstanding objections will be discussed during the oral proceedings. In this situation, there will be no opportunity given to the Applicant to discuss outstanding objections either in writing or by telephone before the actual Oral Proceedings.

5.3 The Applicant is reminded that the examination procedure is **essentially a written procedure** (Article 94(3) EPC and Rule 71 EPC), meaning that the Oral Proceedings may not be used for the discussion of any complex or substantial amendments filed after the deadline according to Rule 116(1) EPC.

5.4 If the Applicant intends to submit an excessively large number of requests for amendments, even in the case that these requests are not late within the meaning of Rule 116(1) EPC, it is to be expected that these requests may not be admitted into the proceedings. The Division will consider such a filing as an attempt to delay proceedings and thus a violation of the principles of procedural law generally recognised in the Contracting States (Article 125 EPC).

5.5 **Recent case law (e.g. T 497/02; T 915/02; T 676/03; T 21/06; T 574/06; T 1704/06 and T 1237/07) indicates that an Applicant who files amended claims before Oral Proceedings and does not attend them must expect a decision based on objections which might arise against such claims in his absence. The fact that Oral Proceedings are maintained indicates that objections are still outstanding and need to be discussed at the Oral Proceedings.**

5.6 Finally, the Applicant's attention is drawn on the fact that the Examining Division is of the provisional opinion at least some of the objections raised in paragraph 3 above are such that there appears to be no possibility of overcoming them by amendment. Refusal of the application under Article 97 (2) is therefore to be expected.

An appealable decision could likewise be achieved by requesting a **decision according to the state of the file** in order to increase procedural effectiveness and to avoid additional costs (see the Guidelines, C-VI, paragraph 4.5).